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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,449	09/22/2003	Alfred Weber	SCH-1743 CI	6844

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/665,449	Applicant(s) WEBER ET AL.	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-56, 59-65, 68-70, 73, 74 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-56, 59-65, 68-70, 73, 74 and 78-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/509,608.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 54-56, 59-65, 68-70, 73-74 and 78-81 are pending.

Applicants' amendment filed February 15, 2007 is acknowledged. Applicant's response has been fully considered. Claims 54-56, 59-65, 68-70 and 73-74 have been amended, claims 57, 58, 66, 67, 71, 72, 75 and 76 have been cancelled, and new claims 78-81 have been added. Therefore, claims 54-56, 59-65, 68-70, 73-74 and 78-81 are examined.

Withdrawn Informalities

2. The previous objection to the specification, regarding abstract, is withdrawn in view of applicants' submission of a new abstract in the amendment filed February 15, 2007.

Withdrawn Claim Objections

3. The previous objection to claims 54, 55, 56-62, 63, 64, 68, 70 and 71-76, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 8 in the amendment filed February 15, 2007.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 65-67 under 35 U.S.C. 101, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claims, and applicants' response at page 8 in the amendment filed February 15, 2007.

Withdrawn Claim Rejections - 35 USC § 112

5. The previous rejection of claims 54, 55, 63 and 65-67 under 35 U.S.C. 112, second paragraph, regarding the term "its intermediate products", being dependent from a cancelled claim, no antecedent basis, or no method steps, is withdrawn in view of applicants' amendment

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to the claim, applicants' cancellation of the claims, and applicants' response at page 9 in the amendment filed February 15, 2007.

6. The previous rejection of claims 63, 66 and 67 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' cancellation of the claims, and applicants' response at pages 9-11 in the amendment filed March 6, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Previous rejection of claims 54, 55, 63-65 and 68-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained, and claims 56, 59, 60-62, 73, 74 and 77-80 are added to the rejection.

8. Claims 54-56, 59-65, 68-70, 73-74 and 78-81 are indefinite because the claim recites the terms "the gene of the HMG-Co-reductase (t-HMG)", "the gene of the squalene synthetase (ERG9)", "the gene of the acyl-CoA; sterol-acyltransferase (SAT1)", "the gene of squalene epoxidase (ERG1)", "the t-HMG gene", "the SAT1 gene", or "the ERG9 gene", it is not clear what specific gene the term refers to, e.g., does "the t-HMG gene" refers to the t-HMG gene from *S. cerevisiae* or from other microorganisms? Claims 55-56, 59-65, 73-74 and 78-81 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claims from which they depend.

Response to Arguments

Applicants indicate each of the specified genes leads to the expression of an enzyme which has a specific function. As disclosed in the specification, the function of the claimed genes and the enzymes encoded by such genes are fully recognized in the art (See, page 2, 1st paragraph to page 3, 3rd paragraph of the specification and the disclosure contained in the Examples). Therefore it is not necessary to recite the microorganism from which the claimed gene is derived. One skilled in the art would recognize what genes are defined by ascribing to the function of said genes and/or a product thereof. The specification provides embodiments for the construction, isolation and purification of appropriate vectors comprising said genes derived from a variety of microbial species. A skilled worker would recognize that the genes defined in the claims are not restricted to a particular organism (pages 8-9 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. Since the claims recites the terms such as "the gene of the HMG-Co-reductase (t-HMG)", "the gene of the squalene synthetase (ERG9)", "the gene of the acyl-CoA; sterol-acyltransferase (SAT1)", "the gene of squalene epoxidase (ERG1)", "the t-HMG gene", or "the SAT1 gene", or "the ERG9 gene", which indicate a specific gene of the cited enzyme, and there are many genes of the cited enzyme from a variety of microbial species, it is not clear which gene the term refers to.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 59 and 64-65 are rejected under 35 U.S.C. § 112, first paragraph, enabling the deposit, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To practice the instant methods or to make the claimed products, one of skill in the art is required to use YEpH2, YDpUHK3, and pADL-SAT1 plasmids. The instant specification contains no deposit information concerning these plasmids. To enable the instant claims by enabling the deposit of YEpH2, YDpUHK3, and pADL-SAT1 plasmids, the following items are required: (1) the accession number assigned by the depository, (2) the date of deposit, (3) a brief description of the deposit, (4) the name and full address of the depository (37 C.F.R. § 1.801 - 1.809), and (5) the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants' representative. An alternative to the deposit of the exact plasmids is the deposit of all precursor plasmids required to produce the claimed plasmids as described in the specification.

Response to Arguments

Applicants indicate the specification provides adequate guidance regarding the plasmid vectors and/or the yeast strain claimed herein. More specifically, the specification discloses that the plasmid vectors species comprising one or more genes recited in Applicants' claim 54 can be obtained using techniques that are routinely available to one of ordinary skill in the art. Method for constructing the claimed plasmid vectors are provided in pages 20-21 of the instant specification. Restriction sites and maps of the claimed vectors are also provided. See, for

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example, Figs. 1-3 of the specification. A cursory search reveals that YEpH2, YDpUHK3, pADL-SAT1, and YEp13 are widely recognized in the art of microbiology. The specification provides adequate guidance on the state of the art prior on ergosterol metabolic genes prior to the filing of the instant application (See, pages 2-4 of the specification). The specification also provides adequate guidance on the Yeast strain AH22 and methods for generating transformants comprising one or more claimed genes (See, pages 22-24 and pages 24-26), and the cited reference of Basson et al., Fegueur et al., Yu et al., Jandrositz et al. in the specification, provide detailed disclosure on the genes involved in ergosterol metabolism. A search on Journal of Biological Chemistry with *S. cerevisiae* AH22 revealed more than 20 scientific publications prior to the earliest priority date of the instant application, a parallel search in PUBMED with the search term "Yeast strain AH22" revealed more than 20 publications (See enclosed Exhibits). Therefore, the specification, further in view of the references cited therein, provides adequate guidance on the structure of claimed plasmid vectors and/or the microbe strains. Furthermore, the specification need not provide expressed guidance on the structural features of the claimed plasmid species, as such were not only known, but also commercially available to a skilled worker before the application was filed (pages 9-11 of the response).

Applicants' response has been fully considered, regarding yeast strain AH22, applicants' arguments are found persuasive, thus the rejection is withdrawn. However, regarding YEpH2, YDpUHK3, pADL-SAT1, and YEp13, the arguments are not found persuasive because of the following reasons.

Plasmid YEpH2 (see Example 1 in the instant specification) requires the use of tHMG cloned using primers (SEQ ID NOs: 1 and 2, enabled), pUC 19 (commercially available and

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enabled), pPT2b (Lang and Looman, 1995), and YEp13 (Fischhoff et al., 1984); no evidence of the commercial availability of pPT2b or YEp13 is provided.

Plasmid YDpUHK3 (see Example 1 in the instant specification) requires the use of YEpH2 (so all of the above) and YDpU (Berben et al., 1991); no evidence of the commercial availability of pPT2b, YEp 13, or YDpU is provided.

Plasmid pADL-SAT1 (see Example 2 in the instant specification) requires the use of SAT1 cloned using primers (SEQ ID NOs: 3 and 4, enabled), pGEM-T (Mezei and Storts, 1994), pADH1001 (unknown source), and YEp13 (unknown source); no evidence of the commercial availability of pGEM-T, pADH1001 or YEp13 is provided. Moreover, the particular fragment of YEp13 containing the LEU2 gene is not disclosed so its exact nature could not be reproduced without undue experimentation.

Thus, by Applicants arguments, to enable plasmids YEpH2 and YDpUHK3 without Applicants' deposit, a showing of the public availability of pPT2b, YEp13, and YDpU is required. To enable plasmid pADL-SAT1 without Applicants' deposit, a showing of the public availability of pGEM-T, pADH1001 and YEp13 is required as well as a better description of the LEU2 fragment of YEp13 such that pADL-SAT 1 can be exactly duplicated and, thus, be in the hands of the public without undue experimentation.

Conclusions

10. No claims are allowed.

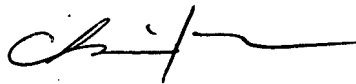
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

May 8, 2007